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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,607	04/08/2004	Joachim Ernst Kramer	P06300US02-PHI 1483	9485

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/820,607	Applicant(s) KRAMER, JOACHIM ERNST	
	Examiner Medina A. Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/13/05 has been entered.

Applicant's amendment filed 10/13/05 has been entered. Claims 12-36 are added. Therefore, claims 1-36 are pending and are examined.

Claim Objections

At claim 16, it is suggested that "wherein seed is allowed to form" be replaced with ---and harvesting seed---, for clarification.

Claim Rejections - 35 USC § 112, 2nd

Claims 13-14, 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: repeating steps (c) and (d) three or more times to produce backcross progeny with at least 95% of the alleles of the inbred line. Dependent claim 14 is included in the rejection.

Claims 25 and 27-30 improperly depend from claim 15. The claims do not incorporate all elements of the parent claim 15. The plant of parent claim 15 does not contain a single locus conversion, a dominant or recessive allele/transgene. Therefore, claims 28- 30 do not incorporate all elements of the claim from which it depends.

Claims 28-30 are indefinite in the recitation of "male sterility" because the plant of parent claim 15, PH94T, is male fertile. See pages 27 of the specification (line 37, where the plant is characterized as having pollen shed rated as 5.3 (on a scale from zero being male sterile to 9 being heavy pollen shed). The plant of claims 28-30, however, is not male fertile. Clarification is required to more clearly define the metes and bounds of the claims.

Claim 34 is indefinite in the recitation of "using" without any active, positive steps delimiting how this use is actually practiced. Since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

Written Description

Claims 1-12 remain rejected and new claims 17-21, 23, 25-28, 31-32, and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 07/13/05, and is now applied to the new claims.

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Applicant's arguments filed 10/13/05 have been considered but are not deemed persuasive.

Applicant reiterates that the written description of the claimed invention has been fulfilled by actual reduction to practice of F1 hybrids produced from inbred maize line PH94T; by the deposit of common identifying characteristics; by the morphological description of the inbred; and by the description of SSR marker profiles of the inbred as shown in Table 4 of the specification. Applicant asserts that both *Enzo Biochem. Inc.*, (323 F3d at 965, 63 U.S.P.Q. 2d at 1613(2002)) and *Ex Parte C*, 1992 (WL 515817 p. *5, 27 USPQ.2d 1492, 1496 (B.P.A.I 1992), confirmed that a deposit of seed is sufficient to comply written description requirements (response, pp. 9-10).

These arguments are not persuasive because while a deposit of seed is sufficient to describe seed of the inbred, F0 plants produced from the deposited seed, and methods of producing F1 hybrids from said F0 plants; the deposit does not provide written description to hybrids including F1 generation produced from the inbred. Unlike in the instant application, the claims considered in *Ex parte C* (1992) didn't involve F1 hybrid where one of the parents involved in the breeding was unknown. Self-pollinating the soybean plant from the deposited seed produced the first generation seed of the claims in *Ex parte C*. In the instant application, hybrid plants and seed of the claims are produced by crossing plants of the inbred maize PH94T with any distinct unknown inbred maize line. Hybrids that do not share both of the same parents will not have the same traits and the fact that they share one set of chromosomes from PH94T does not provide any description for the hybrids.

And unlike in *Enzo Biochem, Inc* (2002), here the deposited seed of inbred PH94T does not correspond exactly to the claimed seed or plant comprising at least one set of the chromosomes of inbred PH94T, including F1 hybrid seed/plant, as stated in the last Office action of 07/13/05. The function of the plant grown from a PH94T seed is correlated with the structure of its entire genome. The functions of the claimed hybrid plants grown from the claimed hybrid seeds are correlated with the structures of their entire genomes, not just the set of chromosomes inherited from PH94T. Applicant has provided no evidence to support the conclusion that the function of the claimed hybrid correlated to the set of chromosomes originating from the deposited PH94T. Therefore, neither the decision in *Enzo Biochem, Inc* (2002) nor the decision in *Ex parte C* (1992) appear to support Applicant's position.

Applicant further cites *J.E.M Ag Supply, Inc* (534 US 124, 143; 122 S.Ct 593, 604; 60 USPQ 2d 1865, 1873 (2001) to support of that argument that a patent on an inbred line protects the line as well as all hybrids produced from the inbred (response, p. 10).

This is not found persuasive. In *JEM Ag Supply, Inc. v. Pioneer Hi-Bred International*, (2001), the court also stated " (H)ybrid seeds are produced by crossing two inbred corn plants and are especially valuable because they produce strong and vibrant hybrid plants with selected highly desirable characteristics". The court refers to hybrids produced from two known inbred corn plants rather than hybrids produced with only one known parent as claimed in the instant specification.

Applicant reiterates that the claimed hybrids are in accordance with *Eli Lilly* standard based on the assertion that the deposited seed of the inbred and SSR profiles of Table 4 will allow one skilled to identify the F1 hybrids. Applicant asserts that inbred PH94T genotype preserved in the hybrid provides structural characteristics sufficient to distinguish them from hybrids that do not made with PH94T (response 11-12).

This is not persuasive for the reasons of record. The specification does not describe the functions (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the functions of the hybrids with the structure of the genetic complement or the set of chromosomes from PH94T. In *Eli Lilly*, the members of the genus shared a common function. The claimed hybrids do not have the entire genomic characteristics of PH94T, but only one set of chromosomes of PH94T. This one set of chromosomes of PH94T will interact with another set of chromosome from the other non-PH94T parent. Even if one assumes that the SSR profile is a proper way to describe a hybrid, then it will require the SSR profiles of both parents to identity the hybrid not just the SSR profile of the one of the parents. The instant specification fails to describe the SSR profile of other parents involved in the breeding.

Applicant also reiterates that the genus of F1 hybrid seed and plants encompassed by claims 1-10 all share the common structural attribute of having a complete set of the unique chromosomes of PH94T, and that each F1 hybrid produced from PH94T will comprise this unique set of chromosome of PH94T. Applicant also asserts that this unique set of chromosomes described in the SSR profile of Table 4 of the specification is sufficient to describe the genus of claimed hybrids. Applicant further

asserts that the written description requirement does not mandate a description via morphological and physiological traits.

These are not persuasive for the reasons of record. Hybrid produced from inbred will receive one set of chromosomes from each inbred parent. However, where the breeding involves unknown various non-PH95 parents, all F1 hybrids will **not** receive the same set of chromosomes from each of the parents involved in the breeding. For example, if PH94T carries two recessive alleles for insect resistance, it will be susceptible to insects. If it is crossed to another inbred with a recessive allele at that locus, the hybrid will also be susceptible to insects. If the other chosen inbred has a dominant allele at that locus, the hybrid will be insect resistant, if simple Mendelian genetics governs the inheritance of this trait. Each inbred possesses thousands of genetic loci governing thousands of traits, including silk color, lodging resistance, leaf color, stalk color, disease resistance, stalk stiffness, waxy starch, days to maturity, etc., with a dominant or recessive allele at each locus. It is the interaction between the two sets of alleles from both parents that determine the morphological and genetic characteristics of the F1 hybrid. Applicant also has provided no evidence that these F1 hybrids are reproducible.

Applicant argues that an exemplary hybrid produced from inbred PH94T is sufficient to provide written description of the claimed genus based on the assertion that the cells and/or chromosomes are present in the genus of F1 hybrid made with PH94T. Applicant cites *Ex parte Garing* (BPAI 2005) to support his position (response, p. 12).

This is not found persuasive for the reasons of record. Hybrids that do not share both of the same parents will not have the same traits and the fact that they share one set of chromosomes from PH94T does not provide any description for the hybrids. PH94T plants can be crossed with any other inbred maize plant to produce the claimed hybrids. The claimed hybrids then will express a combination of set of alleles that are different from each other, and which are also different from those expressed by PH94T. That all hybrids will inherit cells and/or chromosomes from PH94T does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids.

Regarding the decision in *Ex parte Garing* (BPAI 2005), the Examiner notes that the opinion in support of the decision is neither for publication nor guidelines for all patent application claiming hybrids of corn inbred. Examiner also notes that every application is examined upon its own merits and according to USPTO policy at the time the application is filed. MPEP 2163 states, "(c)ompliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991)".

Applicant correctly states the legal standard for the written description requirement. However, a claim drawn to a genus of hybrid plant/seed would require description via morphological and physiological of a representative number of plants/seed that falls within the genus claimed. The instant specification fails to describe a representative number of hybrids of the genus claimed. The specification only compares performance data for a hybrid containing PH94T with each of three other

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hybrids, namely hybrids 3905, 39D81, and 38R69 (pages 61-67). Applicant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred PH94T with any and all other inbred or hybrid maize plants. Therefore, the requirement is proper and is within USPTO's Written description Guidelines.

Applicant's comment regarding to *Ex parte Tanksley* (the citation is incomplete) cited at the paragraph bridging pages 13 and 14 of the response is noted. However, it is unclear the relevance of Tanksley in the instant application. The Examiner has not required that Applicant list specific morphological and physiological characteristics of the hybrids in the claims for clarity. The instant claims are rejected under 35 U.S.C. 112, first paragraph because the specification does not provide written description of the claimed genus of hybrid plants/seed.

New claims 17-20, and 24, drawn to hybrid maize seed and hybrid maize plants are rejected for the same reasons as set forth in the last Office action for claims 1-12. New claims 13-14, 21 and 23 are included in the rejection because the SSR loci listed in Table 4 are not structurally described. Without the descriptions of the sequences of the markers, one cannot confirm their presence in hybrids as asserted by Applicants. Also, step (e) of claim 11 fails to describe the number of times steps (c) and (d) have to be repeated to produce backcross progeny plants with the desired trait and essentially all the morphological and physiological characteristics of the inbred.

Claims 25-27, drawn to a maize plant of inbred PH94T further defined as having a genome with single locus conversion, are rejected because the claims do not place any limitation on the trait conferred or affected by the single locus conversion. The claims also broadly encompass single loci that have not been discovered or isolated.

Claims 28-30 are rejected. The specification indicates a single locus conversion of PH94T occurs when DNA sequences are introduced into the plant by traditional breeding techniques such as backcrossing (paragraph bridging pages 31-32). However, the specification provides no description of any plant produced by classical breeding methods such as backcrossing or recurrent selection. No other maize plant ("donor parent") exhibiting a single desired trait for use in backcross breeding has actually been disclosed and described, and no resulting progeny from such a cross has actually been disclosed or described. Furthermore, the individual genes conferring the desired traits have not been characterized, and the genes for several of the contemplated traits, i.e. "improved nutritional quality" and "yield stability" as claimed in claim 28 have not been isolated. In fact, the genes conferring such traits are thought to be quantitative in nature, i.e. governed by multiple genes, often occurring on different chromosomes, which additively contribute to the desired effect.

Claims 31-32 are included in the rejection because the claims read on a method for crossing PH94T with a multitude of non-exemplified breeding partners which have not been characterized either morphologically or genetically. Only PH94T has been morphologically described in the specification, as possessing a particular combination of

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traits as set forth in Table 1. PH94T has not been described with regard to its genetic complement, i.e. the particular collection of genes that confer all of the traits it exhibits.

Claims 34-36 are included in the rejection because the claims require the use of a multitude of non-exemplified molecular markers. The instant specification does not characterize or described even one maize molecular marker, with regard to sequence, length or source. Thus, the claims read on a method of using inadequately described products, rendering the method of using such products similarly inadequately described.

Therefore, for all the reasons discussed above and in the last Office action, the claimed invention lacks adequate written description. The rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-16, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 24 of U.S. Patent No. 6, 774, 290. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both the application and the

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patent are directed to maize plants having all the morphological and physiological characteristics of the maize inbred line H7AB and parts of said plants.

Remarks

Claims 1-14, 17-21, 23-36 are deemed free of the prior art, given that the prior art does not teach or fairly suggest a hybrid maize seed/plant produced from the inbred maize PH94T, as stated in the last Office action.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12/7/05

Mai

MEDINA A. IBRAHIM
PATENT EXAMINER

